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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,007	03/30/2004	Jose L. Boyer	03678.0064.CPUS02	6051
27194	7590	10/05/2005	EXAMINER	
HOWREY LLP C/O IP DOCKETING DEPARTMENT 2941 FAIRVIEW PARK DRIVE, SUITE 200 FALLS CHURCH, VA 22042-2924			LEWIS, PATRICK T	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/814,007	<b>Applicant(s)</b> BOYER ET AL.	
	<b>Examiner</b> Patrick T. Lewis	<b>Art Unit</b> 1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>05312005; 07302004</u> . | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Drawings*

1. The disclosure is objected to because of the following informalities: Brief Description of the Figures is objected to because each figure (i.e. Fig. 1-1, Fig. 1-2, etc.) has not been described in the specification.

Appropriate correction is required.

### *Double Patenting*

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-5 and 21-25 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 35 and 37-42 of copending Application No. 09/643,138. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant compounds and compositions are embraced by copending Application No. 09/643,138.

Art Unit: 1623

Application No. 09/643,138 teaches a monophosphate at the 5'-position, an oxygen atom at position D1, the instant purine base incorporating a urea moiety at the 6-position, and a cyclic acetal at positions 2' and 3'.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 6-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 5-34 and 43-46 of copending Application No. 09/643,138. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant method, compounds and compositions are embraced by copending Application No. 09/643,138. Application No. 09/643,138 teaches a monophosphate at the 5'-position, an oxygen atom at position D1, the instant purine base incorporating a urea moiety at the 6-position, and a cyclic acetal at positions 2' and 3'. Said application also teaches the use of the compounds/compositions for preventing diseases or conditions associated with platelet aggregation.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1623

6. Claims 6-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating diseases or conditions associated with platelet aggregation, does not reasonably provide enablement for a method of preventing diseases or conditions associated with platelet aggregation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue".

These factors include, but are not limited to:

1. the breadth of the claims;
2. the nature of the invention;
3. the state of the prior art;
4. the level of one of ordinary skill in the art;
5. the level of predictability in the art;
6. the amount of direction provided by the inventor;
7. the existence of working examples; and
8. the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The instant claims are drawn to a method of treating or preventing diseases or conditions associated with platelet aggregation comprising administering to a subject a

Art Unit: 1623

pharmaceutical composition comprising a compound of Formula Ib'. The USPTO applies to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification. This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. Ordinary, simple English words whose meaning is clear and unquestionable, absent any indication that their use in a particular context changes their meaning, are construed to mean exactly what they say. While the claims of issued patents are interpreted in light of the specification, prosecution history, prior art and other claims, this is not the mode of claim interpretation to be applied during examination. During examination, the claims must be interpreted as broadly as their terms reasonably allow. The ordinary and customary meaning of the term "prevent" is "to keep from happening : AVERT".

Lautenschlager et al. US 4,330,550 (Lautenschlager) is representative of the state of the art at the time of the invention in regards to the prevention of diseases or conditions associated with platelet aggregation. Lautenschlager teaches that anticoagulants have been employed in the prophylaxis of thrombosis. At sufficiently high dosage, anticoagulants prevent the formation of fibrin and thus the formation of a red thrombus, but they cannot affect the initial aggregation of the thrombocytes, that is to say the formation of the platelet-thrombosis.

Art Unit: 1623

The phrase "diseases or conditions associated with platelet aggregation" embraces a variety medical conditions, each having its own set of risk factors. No examples are provided in the instant specification showing the prevention of any disease or condition associated with platelet aggregation. The instant disclosure also fails to provide rationale which would lead one of ordinary skill in the art to predict that diseases or conditions associated with platelet aggregation are prevented using a composition comprising a compound of Formula Ib'. Due to the lack of guidance provided in the specification and the level of unpredictability in the art, one of ordinary skill in the art would not be able to practice the instant invention without undue experimentation.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a compound of Formula Ib or salts thereof; however, Formula Ib has not been defined.

### ***Claim Objections***

9. Claim 23 is objected to because of the following informalities: improper use of quotation marks (thereof"). Appropriate correction is required.

Art Unit: 1623

***Conclusion***

10. Claims 1-25 are pending. Claims 1-25 are rejected. No claims are allowed.




***Contacts***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Patrick T. Lewis, PhD  
Examiner  
Art Unit 1623

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